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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

In re:
OXYCONTIN ANTITRUST LITIGATION

04-md-1603 (SHS)

This document relates to:

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC., and
PURDUE PHARMACEUTICALS L.P.,

Plaintiffs and Counterclaim Defendants,

v.

KV PHARMACEUTICAL COMPANY and
ACTAVIS TOTOWA LLC,

Defendants and Counterclaim Plaintiffs,

v.

THE PURDUE FREDERICK COMPANY,
THE PURDUE PHARMA COMPANY, and
EUROCELTIQUE S.A.,

Counterclaim Defendants.

Civil Action No.: 1:07 Civ. 03972
(SHS)

**ACTAVIS TOTOWA LLC'S MEMORANDUM OF LAW
IN OPPOSITION TO THE DIRECT PURCHASER CLASS PLAINTIFFS'
AND NON-CLASS PLAINTIFFS' JOINT MOTION TO LIFT THE STAY**

In the interest of judicial economy, this Court has stayed all antitrust claims brought directly by the various antitrust plaintiffs and as counterclaims by three of the four remaining generic defendants, Actavis Totowa LLC (“Actavis”), KV Pharmaceutical Company (“KV”) and Apotex Inc. (“Apotex”). The stay was put in place in order to efficiently resolve issues of patent infringement, validity and enforceability prior to addressing the antitrust claims, which are grounded in the patent issues. (See Multidistrict Litigation Order No. 2, March 30, 2006.) Although the Court ruled on the patent enforceability issues in its January 7, 2008 Opinion and Order with respect to the generic defendants, it has not yet addressed whether the patents being asserted by plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. (collectively “Purdue”) are valid and infringed.

Because the validity and infringement of the patents will impact the resolution of the antitrust issues, the Direct Purchaser Class Plaintiffs’ and Non-class Plaintiffs’ (collectively, the “Direct Purchaser Plaintiffs”) joint motion to lift the Court’s March 30, 2006 stay of the antitrust litigation should be denied. As recognized by the Court when it stayed the antitrust claims, the most efficient approach in this proceeding is to allow the patent issues to be decided prior to addressing the antitrust claims. Such a procedure will efficiently utilize the resources of the Court and the parties.

In addition, maintenance of the stay of the antitrust claims will allow the remaining patent issues to be resolved more expeditiously, thus accomplishing the purposes of the Hatch-Waxman Act and potentially opening the OxyContin[®] market back up to generic competition. Purdue’s initiation of the patent infringement litigation has automatically stayed Food and Drug Administration (“FDA”) approval of the proposed generic products of Actavis, KV and Apotex for 30 months. This 30 month stay will be terminated, however, upon an earlier

court decision that the patents at issue are invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii). Allowing the patent issues to proceed expeditiously without being hindered by the complicated and time-consuming antitrust issues is consistent with the purpose of the Hatch-Waxman Act, which is to “get generic drugs into the hands of patients at reasonable prices – fast.” In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991).

BACKGROUND

Beginning in 1999, Purdue filed numerous patent infringement actions to prevent competition for OxyContin®. These actions, including the ones filed against the remaining generic defendants – Actavis, KV, Apotex and Mallinckrodt Inc. (“Mallinckrodt”) – were either filed by Purdue in this Court or transferred and consolidated in this Court pursuant to an order by the Judicial Panel on Multidistrict Litigation (the “MDL Order”). While all of the original actions and many of the later actions involved allegations of patent infringement relating to four patents (U.S. Patent Nos. 5,266,331, 5,549,912, 5,656,295 and 5,508,042), three of the patents at issue expired in October 2007. The one remaining patent (U.S. Patent No. 5,508,042 (“the ‘042 patent”)) is the sole patent asserted by Purdue against Actavis and Apotex.

Starting in January 2004, numerous antitrust actions were brought against Purdue by the Direct Purchaser Plaintiffs and others. These actions were also either filed in this Court or transferred and consolidated in this Court pursuant to the MDL Order.

In response to Purdue’s patent infringement complaints, many of the generic defendants (including Actavis, KV and Apotex) filed counterclaims against Purdue, alleging, among other things, that Purdue violated the antitrust laws by bringing the patent infringement actions. These antitrust counterclaims and the antitrust claims asserted by the Direct Purchaser Plaintiffs have some asserted misconduct in common; specifically, that Purdue obtained its patents by

committing fraud on the PTO. The counterclaims asserted by Actavis and Apotex additionally allege that Purdue improperly engaged in sham litigation by filing suit based upon the '042 patent, knowing that the patent was invalid. (See Actavis' Counterclaims at ¶¶ 38-42; Apotex' Counterclaims at ¶ 47.)

On December 11, 2002, the Court bifurcated the antitrust counterclaims from the patent claims, finding that "bifurcating the issues will lead to expedition and economy," allowing the Court to address the patent issues before the antitrust issues. Following the remand from the Federal Circuit, the Court stayed all of the antitrust claims on March 30, 2006, "[b]ecause disposition of the antitrust issues will be greatly impacted by the determination on remand of the validity of the underlying patent. . . ." (March 30, 2006 Multidistrict Litigation Order No. 2 at ¶ 2.) As the Court explained:

The Federal Circuit's decision to vacate this Court's patent holding puts the Oxycontin litigation in essentially the same position as it was in when the Court initially bifurcated the antitrust and patent claims; for the same reasons that bifurcation was appropriate then, a stay is appropriate now.

(*Id.*) On July 27, 2007, the Court entered an order staying the antitrust counterclaims asserted by Actavis and KV and staying the issues of patent infringement and validity until the enforceability issues were resolved.

Following briefing and argument by KV, Mallinckrodt, Actavis and Purdue, the Court issued its Opinion and Order on January 7, 2008, rejecting the challenge to the enforceability of the Purdue patents and finding that Purdue did not commit inequitable conduct before the PTO. On January 8, 2008, Actavis requested that the stay of the infringement and validity issues be lifted and that a conference be held to discuss an appropriate schedule to resolve the patent issues. On February 12, 2008, Purdue filed a similar request for a status conference to discuss how to proceed on the patent issues. In its letter, Purdue also reminded the Court about the

30-month stays that were in place, which prevent FDA from approving the generic products of Actavis, KV and Apotex until at least June 2009 or an earlier court decision finding the '042 patent invalid or not infringed. The requests from Actavis and Purdue are currently pending before the Court.

ARGUMENT

I. The Stay of the Antitrust Claims Promotes Judicial Economy

As discussed above, this Court has on multiple occasions ruled that a stay of the antitrust claims is appropriate. A stay of the antitrust claims made sense then, and it continues to make sense now. Keeping the stay in place will promote judicial economy and the efficient use of the parties' (and the Court's) resources because it will allow the patent issues underlying the antitrust claims to be resolved first, before the antitrust claims are tackled. Given these efficiencies, it is "now standard practice" for courts to separate and stay antitrust counterclaims until the underlying patent claims are resolved. In re Innotron Diagnostics, 800 F.2d 1077, 1084 (Fed. Cir. 1986).

While the Court has ruled on the enforceability issues in the cases brought against Actavis, KV and Mallinckrodt, the infringement and validity issues have yet to be addressed. Because the validity of the patents underlies at least some of the antitrust claims, it is appropriate to keep the stay of the antitrust claims in place until the patent validity issues are first resolved. Lifting the stay at this time would be counterproductive to the interests of judicial economy.

II. The Stay Promotes Public Policy Underlying the Hatch-Waxman Act

In addition to judicial economy, maintaining the stay of the antitrust issues provides another benefit – the early resolution of the patent infringement and validity issues, independent of and prior to the resolution of antitrust issues. "Proceeding on the antitrust claims

simultaneously with the patent claims may delay resolution of the case by increasing its complexity, whereas many issues will likely be mooted by addressing the patent claims first.” Chip-Mender, Inc. v. The Sherwin-Williams Co., 2006 U.S. Dist. LEXIS 2176, at *38 (N.D. Cal. Jan. 3, 2006). An earlier resolution of the patent issues is consistent with the purpose of the Hatch-Waxman Act, which is to “get generic drugs into the hands of patients at reasonable prices – fast.” In re Barr, 930 F.2d at 76. Moreover, an earlier resolution of the patent issues is consistent with the Hatch-Waxman mandate that the parties “reasonably cooperate in expediting the action.” 21 U.S.C. § 355(j)(5)(B)(iii).

As the Court is aware, when Purdue initiated its patent infringement actions against Actavis, KV and Apotex, FDA approval of their generic versions of OxyContin[®] was automatically stayed for 30 months or an earlier court decision finding the patents invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii). According to Purdue’s February 12, 2008 letter to the Court, the 30 month stays begin to expire in June 2009. Because an earlier decision by this Court finding the ‘042 patent invalid or not infringed will terminate the 30 month stay and allow FDA to approve the generic products, the Court should expedite a resolution of the patent issues. Maintaining the stay of the antitrust issues will advance this cause, consistent with the policies underlying the Hatch-Waxman Act.

CONCLUSION

For the foregoing reasons, the Direct Purchaser Class Plaintiffs' and Non-Class Plaintiffs' Joint Motion to Lift the Stay should be denied, and this Court should establish an expeditious schedule to resolve the remaining patent issues.

Dated: March 7, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2008, a true and correct copy of the foregoing document was filed electronically and is available on the ECF system for downloading. I also certify that on March 7, 2008, I caused a copy of the foregoing document to be served on the counsel listed below by the specified method:

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